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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,308	09/01/2004	Atsushi Nakanishi	3030 US0P	8302

7590 08/06/2007

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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
08/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,308	NAKANISHI ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,14 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 43* is/are allowed.

6)☒ Claim(s) *14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 September 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's response to the office action mailed on 11/15/2006, including arguments/remarks and amendments to the claims, was received on 4/16/2007 and has been entered into the record.

2. Claims 1, 14, and 43 are currently pending and are the subject of this office action.

Claim Objections

Objection to claims 1 and 14 regarding the term "having", and claim 14 for an extra space between the word "protein" and the subsequence comma, as set forth on pages 2-3 of the office action mailed on 11/15/2006, is *withdrawn* in response to Applicants' amendments to the claims to recite "comprising" or "consisting" in place of "having", and the amendment to remove said extra space.

Specification and Drawings

The drawings submitted on 9/1/2004 contain figures showing the amino acid sequences of various proteins. Specifically, Figures 1-2, 5, and 7-8 recite sequences that have not been identified by sequence identifier. Furthermore, the brief description of the drawings, on pages 5-8 of the specification, also does not identify the sequences by SEQ ID NO.

When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and a sequence identifier ("SEQ ID NO: X") must be used either in the drawing or in the Brief Description of the Drawings. See MPEP 2422.02. In the instant application, sequence identifiers must be provided for the sequences appearing in Figures 1-2, 5, and 7-8. Appropriate correction is required.

Furthermore, it is noted that the sequence listing submitted on 9/1/2004 does not contain sequence listings for the SLC21A12 and OATPRP4 proteins. Applicants must furnish a new

sequence listing for all recited sequences, including sequences for the SLC21A12 and OATPRP4 proteins.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Rejection of claims 1 and 14 under 35 USC § 101, as not being supported by a specific, substantial and credible asserted utility or a well-established utility, as set forth on pages 3-6 of the prior office action mailed on 11/15/2006, is *withdrawn*.

In the response received on 4/16/2007, the Applicants argue that the specification asserts that the claimed protein is a member of the organic anion transporter family, and the disclosure of (Mikkaichi *et al*, *PNAS*, 2004, Vol. 101, pages 3569-3574) provide proof that the claimed protein is indeed an organic anion transporter protein, and is responsible for the transport of digoxin, oubain, thyroid hormone, cAMP, and methotrexate. The Applicants also argue that Mikkaichi *et al* confirms that the claimed protein is expressed in human kidney tissue, and that expression of the claimed protein is decreased in three different models of kidney disease. Therefore, the Applicants argue that the claimed protein can be used as a diagnostic marker for kidney disease.

In light of these arguments and the disclosure of Mikkaichi *et al*, the rejection under 35 U.S.C. 101 is withdrawn.

Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejections withdrawn

Rejection of claim 1 under 35 USC § 112, first paragraph, regarding lack of enablement for the protein of SEQ ID NO: 1, as set forth on page 6 of the prior office action mailed on 11/15/2006, is *withdrawn* in response to Applicants' arguments that the protein of SEQ ID NO: 1

is an organic anion transporter protein which can function as a diagnostic marker for renal disease, and thus a person of ordinary skill in the art would know how to make and use the protein.

Rejections maintained

Claim 14 *remains rejected* under 35 USC § 112, first paragraph, regarding lack of enablement for a pharmaceutical composition comprising the protein of SEQ ID NO: 1, as set forth on page 6 of the prior office action mailed on 11/15/2006.

In the response received on 4/16/2007, the Applicants argue that the claimed invention has utility under 35 U.S.C. 101 because the claimed protein can be used as a diagnostic marker for renal disease, and therefore the specification is enabling. As discussed *supra*, the one of ordinary skill in the art would know how to make and use the protein of SEQ ID NO: 1 in such a manner. The Applicants also assert that the claimed protein can be used in methods of treating renal disease, either by increasing the levels of the protein, or the activity of the protein. However, the specification does not provide guidance or examples showing any specific disease that can be treated by administration of the protein of the instant invention. The recitation of a "pharmaceutical composition" implies that the composition is useful in a method of treating disease, and thus the breadth of the claim is excessive because it reads on a composition for treatment of a large number of potential diseases. Although the specification teaches that expression of the protein of SEQ ID NO: 1 is decreased in 3 models of renal disease, there is no disclosure that increasing the levels of the protein would influence the outcome of any renal disease. There is no identification of any pathological role for the instantly claimed protein in any disease, or any disclosure of whether or not renal disease occurs because expression of SEQ ID NO: 1 is decreased, or if the decreased expression is a secondary, indirect effect of some other pathological mechanism. Furthermore, there are no examples or guidance teaching how the protein of the instant invention can be administered, or what doses would be effective to treat renal disease. For these reasons, a person of ordinary skill in the art would not be able to make and use a "pharmaceutical" composition comprising or consisting of the protein of SEQ ID NO: 1 without further, undue experimentation.

Conclusion

Claims 1 and 14 are allowable.

Claim 14 is not allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
Art Unit 1646

/Robert S. Landsman/
Primary Examiner, Art Unit 1647